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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,862	04/14/2004	David William End	JAB 1626-Div 3	6191
27777	7590	08/10/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KWON, BRIAN YONG S	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,862

Applicant(s)

END ET AL.

Examiner

Brian S. Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/14/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgement is made of applicant's submitting of the information disclosure statement (IDS) on 04/14/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement (IDS) has been considered by the examiner.
2. With respect to "PCT International Search Report dated 09/23/01998 for PCT Appln NO. PCT/EP98/03182" and "PCT International Search Report dated 09/23/01998 for PCT Appln NO. PCT/EP98/03182" in the submitted PTO-1449, the information disclosure statement filed May 09, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an apparatus comprising a transluminal device and a composition of formula (I), a pharmaceutically acceptable acid or base addition salt thereof, does not reasonably provide enablement for "a stereoisomeric form thereof". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Art Unit: 1614

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The instant claims are drawn to an apparatus for inhibiting smooth muscle cell proliferation comprising a transluminal device and a composition of formula (I), a stereoisomeric form, a pharmaceutically acceptable acid or base addition salt thereof. The specification defines that "stereochemically isomeric forms" refers to "all possible compounds made up of the same atoms bonded by the same sequence of bonds but having different three-dimensional structures which are not interchangeable, which the compound of formula (I) may possess. Unless otherwise mentioned or indicated, the chemical designation of a compound encompasses the mixture of all possible stereochemically isomeric forms which said compound may possess" (page 5, lines 11-20).

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright, 458 F. supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); *Aff'd* 584

Art Unit: 1614

F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5(BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of compositions of adrenocorticotrophic hormones was unpredictable art; In re Wright, 999 F.2d 1577, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of compound(s) in inhibiting smooth muscle cell proliferation prior to filling of the instant invention was an unpredictable art.

The claims are very broad due to the vast number of possible compounds of that are described as being "a stereoisomeric form thereof". The instant claims cover "stereoisomeric form" of formula (I) that are known to exist and those that may be discovered in the future, for which there is no enablement provided.

Although the specification discloses sufficient number of compounds represented by the formula I which exists in racemic mixture (\pm), the specification fails to provide sufficient number of examples of "stereoisomeric form" (Table 1). Nor, the specific provide how to make or synthesize "stereoisomeric form" of formula I. As discussed above, the scope of the instant claimed "stereoisomeric form" of formula I covers "all possible compounds made up of the same

Art Unit: 1614

atoms bonded by the same sequence of bonds but having different three-dimensional structures which are not interchangeable, which the compound of formula (I) may possess". Although some optical isomers are made by simple isolation procedure, many stereoisomers of drug(s) requires high level of skill in separating, quantitating and predicting the pharmacokinetic and biological characteristics of each isomer (see Anal Biochem, 1988, 1; 168(2):398-404). Therefore, without sufficient guidance from the instant specification how to make, quantitate and determine the pharmacokinetic and biological activity of "stereoisomeric form" of formula I, the skilled artisan would have to undergo an undue amount of experimentation to make the claimed product encompassed by the instant invention. As discussed in preceding comments, the instantly claimed "stereoisomeric form" of formula I necessitates an exhaustive search for the embodiments suitable to practice the claimed invention.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fishcher, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575.

Art Unit: 1614

As discussed above, considering above factors, especially the “sufficient working examples”, “the level of skill in the art”, “the relative skill and the unpredictability in the pharmaceutical art”, “breadth of the claims” and “the chemical nature of the invention”, one having ordinary skill in the art would have to undergo an undue amount of experimentation to make the claimed “stereoisomeric form” of formula I that is useful in inhibiting smooth muscle proliferation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 20-27 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6743805.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the present overlaps with the patent.

With respect to the obviousness of claims 20 and 24-27 over the claims 1-5 of US’805,

Art Unit: 1614

Since the disclosure of a species (i.e., stent) in US'805 anticipates a claim to a genus containing species (i.e., transluminal device or apparatus), the patent makes obvious the instant invention.

With respect to the obviousness of claim 21 over the claims 1-5 of US'805,

Both the instant application and the patent are directed to the stent covered with the compound of the formula. Although wording of the claims is slightly different to each other, the patent makes obvious the instant claims.

With respect to the obviousness of claim 22 over the claims 1-5 of US'805,

The statement of intended use or purpose is not limiting to the interpretation of the product claim since such property or characteristic is deemed to be inherent to the product, i.e., it was always there. Thus, the patent makes obvious the instant claims.

With respect to the obviousness of claim 23 over the claims 1-5 of US'805,

“Stent” is defined as “a slender thread, rod, or catheter inserted into a tubular structure, such as a blood vessel, to provide support during or after anastomosis” (Thefeedictionary.com, 2005). Since the disclosure of a species (i.e., stent) in US'805 anticipates a claim to a genus containing species (i.e., a catheter), the patent makes obvious the instant invention.

Conclusion

5. No Claim is allowed.

Art Unit: 1614

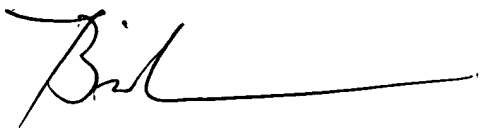
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in dark ink, appearing to read 'Brian', followed by a long horizontal line extending to the right.